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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,520	07/20/2001	Barbara L. Hempstead	19603/2595	9715

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EXAMINER	
NICKOL, GARY B	
ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 12/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/830,520	HEMPSTEAD ET AL.	
	Examiner	Art Unit	
	Gary B. Nickol Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above claim(s) *1-6,11-13,17,20-25,28 and 31-54* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-10,14-16,18,19,26,27,29 and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The Election filed October 17, 2002 (Paper No. 7) in response to the Office Action of September 17, 2002 is acknowledged and has been entered.

Claims 1-54 are pending in the application.

Claims 1-6, 11-13, 17, 20-25, 28, and 31-54 have been withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to non-elected inventions.

Claims 7-10, 14-16, 18-19, 26-27, and 29-30 are currently under prosecution.

Upon reconsideration, the species election between cardiac ischemia, atherosclerosis and a stroke is withdrawn. Furthermore, the species election between BDNF, NT3 and NT4 is withdrawn.

Applicant's election with traverse of Group 4, claims 7-16, 18-19, 26-27, 29-30 in Paper No 7 is acknowledged. The traversal is on the ground(s) that all the inventions are linked as to form a single general inventive concept involving a trk receptor ligand or an inhibitor thereof. Applicants further disagree that the "allowed combinations do not include multiple methods" because the combination of different categories as set forth in the restriction requirement are illustrations of particular situations as described in Annex B, Part 1 of the PCT Administrative Instructions. This argument has been considered but is not found persuasive. All of the claims encompass "multiple uses" with different special technical features for the reasons set forth in Paper No. 5 and are therefore not illustrative of particular situations as described in Annex B,

Part 1 of the PCT instructions. The special situations described in Annex B, Part 1 do not include multiple uses and therefore restriction is proper according to the rule set forth in 37 CFR 1.475(d). For these reasons the restriction requirement is deemed to be proper and is therefore made FINAL.

Specification

The specification is objected to for the following reason: The specification on page 1 should be amended to reflect the priority status of the present application, for example:

This application claims benefit of US provisional application 60/105,928, filed October 28, 1998, now abandoned.

The specification is further objected to on page 9, line 16 for reciting "Figures 6A-I" as Figure 6 only appears to include Figures 6A-"G".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an

international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 7-10, 14-16, 18-19, 26-27, and 29-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Alps *et al.* (US Patent No. 5,733,871, March 1995).

The claims are broadly drawn to method for treating a pathological disorder in a patient comprising administering a trk receptor ligand in an amount effective to treat the pathological disorder by inducing angiogenesis (Claim 7); wherein said pathological disorder is cardiac ischemia (Claim 8); wherein said pathological disorder is a non-cardiac vascular disorder selected from the group consisting of atherosclerosis, renal vascular disease, and stroke (Claims 9-10); wherein said trk receptor ligand is a trk B receptor ligand (Claim 14); or a trk C receptor ligand (Claim 15); wherein said trk receptor ligand is selected from the group consisting of BDNF, NT-3, NT-4, and recombinant and small molecule mimics thereof (Claim 16). The method further comprises delivering a nucleic acid sequence encoding the trk receptor ligand (Claim 18); and various routes of administration as claimed in Claim 19.

The claims are further drawn to a method for treating a pathological disorder in a patient comprising administering a trk receptor ligand in an amount effective to treat the pathological disorder by promoting vessel growth or stabilization wherein said pathological disorder relates to endothelial apoptosis or necrosis (Claims 26-27); wherein said administering comprises

delivering a nucleic acid sequence encoding said trk receptor ligand (Claim 29); and various routes of administration as claimed in Claim 30.

US Patent No. 5,733,871 teaches methods of treating pathological disorders in patients who are suffering from non-cardiac vascular disorders (i.e, strokes) or cardiac ischemia (i.e, cardiac arrest) (column 4, lines 55+). Since ischemia is a deficiency of blood in a tissue due to functional constriction or actual obstruction of a blood vessel (column 6, lines 63+), it is assumed for examination purposes that cardiac ischemia encompasses cardiac arrest since a cardiac arrest can result from the actual obstruction of a blood vessel. Furthermore, the patent teaches that common causes of brain infarcts (i.e, non-cardiac vascular disorders) are caused by "emboli within cerebral vessels, arteriosclerotic vascular disease and the inflammatory processes" (column 7, lines 25+) which encompasses an atherosclerotic disorder. The patent further teaches that these disorders can be treated following intravenous administration of certain neurotrophins including BDNF, NT3 or NT4 (abstract, column 1, column 5). Although the patent does not characterize such neurotrophins as "trk receptor ligands", the specification clearly teaches that such neurotrophins are indeed trk receptor ligands (specification, pages 11-12) that bind to trkB and trkC receptors. Furthermore, the patent teaches that the administration of such neurotrophins can be administered comprising delivering a nucleic acid sequence encoding the trk receptor ligand (column 6, lines 52).

The claims are further drawn to a method for treating a pathological disorder including those disorders which "relate to endothelial apoptosis or necrosis". The specification teaches that "vasculitis" is one example of such a disorder (page 18, line 8). However, since

pathological disorders such as strokes and brain infarctions may be caused by the actual obstruction of a blood vessel, such obstructions would relate to endothelial cell death or necrosis since they cause tissue damage wherein inherently such damage would relate to endothelial cell death or necrosis. Furthermore, according to the online version of Stedman's Medical Dictionary "vasculitis" is a synonym of angiitis which is characterized as the inflammation of vessels including blood vessels or lymphatic vessels. Thus, it is further assumed for examination purposes, that strokes and cardiac ischemia encompass vascular disorders such as vasculitis because of the inflammatory process associated with vessel obstruction.

The patent further characterizes that some neurotrophins are also capable of promoting "blood vessel restoration" (column 5, lines 1+). Although the patent does not characterize that specific trk receptor ligands such as BDNF, NT3 or NT4 induce angiogenesis or promote vessel growth or stabilization, inherently the in-vivo administration of such neurotrophins to those populations having a pathological disorder as set forth above would induce angiogenesis or promote vessel growth or stabilization. Thus, the patent teaches the administration of the claimed compounds to the same population of patients as claimed, with the same route of delivery as claimed and inherently such compounds would effectively induce angiogenesis or promote vessel growth or vessel stabilization.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol, Ph.D.
Examiner
Art Unit 1642

GBN
December 19, 2002